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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/537,103	03/10/2006	Ian Wilson	PZ02101	1240

36335 7590 01/03/2011

GE HEALTHCARE, INC.
IP DEPARTMENT 101 CARNEGIE CENTER
PRINCETON, NJ 08540-6231

EXAMINER	
PERREIRA, MELISSA JEAN	

ART UNIT	PAPER NUMBER
1618	

MAIL DATE	DELIVERY MODE
01/03/2011	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/537,103	WILSON ET AL.	
	Examiner	Art Unit	
	MELISSA PERREIRA	1618	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *28 October 2010*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1,6,11,12,14 and 21-26* is/are pending in the application.

4a) Of the above claim(s) *6,11,12 and 14* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1 and 21-26* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Claims 1,6,11,12,14 and 21-26 are pending in the application. Claims 6,11,12 and 14 are withdrawn. Any objections and/or rejections from previous office actions that have not been reiterated in this office action are obviated.

New Grounds of Rejection Necessitated by the Amendment

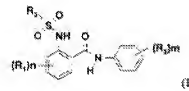
Claim Rejections - 35 USC § 103

1. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

2. Claims 1 and 21-26 are rejected under 35 U.S.C. 103(a) as being unpatentable over Weinstock et al. (WO00/78145A1) in view of Edwards et al. (WO02/067761).

3. Weinstock et al. (WO00/78145A1) discloses sulphonamidobenzamide macrophage scavenger receptor antagonists (MSRA) (below) for treating cardiovascular disease including but not limited to atherosclerosis, coronary artery disease, renal disease, thrombosis, transient ischemia, etc. (abstract; p2, lines 26+; p3, lines 8+). R_1 and R_2 may be halo, hydrogen, alkyl, etc.; R_3 may be R_1aryl, etc. wherein R_1 is halo (p3, lines 8-20). The MSRAs may be formulated as pharmaceutical compositions and administered as tablets, liquid preparations, etc. (p11, lines 14+).

4. 

(I)

5. Weinstock et al. does not teach that the at least one halo substituent (R_1 and R_2) is ^{123}I or ^{18}F.

6. Edwards et al. (WO02/067761) discloses detectably labeled macrophage scavenger receptor antagonist (MSRA) complexes for the diagnosis and monitoring of various cardiovascular diseases including but not limited to atherosclerosis, coronary artery disease, renal disease, thrombosis, transient ischemia, etc. (abstract; p37, lines 12-18). The imaging agent disclosed in the present invention is an SR-A antagonist linked to a radioisotope, such as ^{18}F, ^{123}I, etc. (p48, lines 10-20; p49, lines 13-24). The complexes of the disclosure may also include M-C_h-L_n-$(BM)_n$ wherein M is a radionuclide (i.e. ^{99m}Tc, ^{111}In, ^{113m}In, etc.; C_h is a metal chelator (i.e. a N_4 ligand, N_2S_2 ligand); L_n is a linking group; and BM is a MSRA antagonist (p18-23; p26, lines 19+; p50, lines 6+; see claims). Edwards et al. also teaches of kits comprising the MSRAs of the disclosure (claims 38+).

7. At the time of the invention it would have been obvious to one ordinarily skilled in the art to substitute the MSRA antagonist of Weinstock et al. with a radionuclide for the diagnosis and monitoring of various cardiovascular diseases as Edwards et al. teaches that labeled MSRA complexes are used for diagnosing and monitoring cardiovascular diseases.

8. At the time of the invention it would have been obvious to one ordinarily skilled in the art to substitute the radioisotope, such as ^{18}F, ^{123}I, etc. of Edward et al. for the halogen substituent of Weinstock et al. to provide SR-A antagonist imaging agents as

the results are the predictable advantage of both treating and diagnosing/monitoring cardiovascular diseases.

9. Also, at the time of the invention it would have been obvious to one ordinarily skilled in the art to the formulate the detectably labeled macrophage scavenger receptor antagonist (MSRA) complexes of the combined disclosures of Weinstock et al. and Edwards et al. as a pharmaceutical composition as Weinstock et al. teaches that MSRAs may be formulated as such.

10. The imaging moiety of the combined disclosure encompasses the imaging moiety of the instant claims and is capable of the same functions, such as being detected externally in a non-invasive manner following administration of said labeled synthetic MSRA antagonist to the mammal body in vivo and has the same properties.

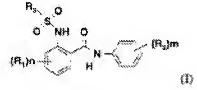
Response to Arguments

11. Applicant's arguments filed 10/28/10 have been fully considered but they are not persuasive.

12. Applicant asserts that Weinstock et al. does not disclose that the MSRA antagonists are labeled with radioactive halogens, let alone specify that these are to be selected from ^{123}I or ^{18}F. Furthermore, Weinstock et al. does not provide any particular motivation to the skilled person to place fluoro or iodo preferably at the positions specified in the instant claims.

13. The reference of Weinstock et al. was not used to teach of the radioactive halogens ^{123}I or ^{18}F but was used to teach of sulphonamidobenzamide macrophage

scavenger receptor antagonists (MSRA) (below) for treating cardiovascular disease comprising halo substituents at the R_1 and/or R_2 positions .

14. 

15. The halo substituent (R_1 and R_2) positions on the MSRA antagonists of Weinstock et al. are identical positions found on the MSRA antagonists of the instant claims.

16. The reference of Edwards et al. was used to teach of detectably labeled macrophage scavenger receptor antagonist (MSRA) complexes for the diagnosis and monitoring of various cardiovascular diseases including but not limited to atherosclerosis, coronary artery disease, renal disease, thrombosis, transient ischemia, etc. wherein the imaging agent/detectably labeled MSRA disclosed in the present invention is an SR-A antagonist linked to a radioisotope, such as ^{18}F, ^{123}I, etc.

17. At the time of the invention it would have been obvious to one ordinarily skilled in the art to substitute the radioisotope, such as ^{18}F, ^{123}I, etc. of Edward et al. for the halogen substituent of Weinstock et al. to provide SR-A antagonist imaging agents as the results are the predictable advantage of both treating and diagnosing/monitoring cardiovascular diseases.

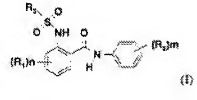
18. Applicant asserts that Edwards et al. provides compounds for in vivo imaging atherosclerosis and vulnerable plaque that comprise an MSRA antagonist linked to a metal chelate, where a metal chelate comprises a metal that is an in vivo imaging

moiety. Suitable in vivo imaging moieties of Edwards et al. include ^{99m}Tc, ^{111}In, ^{113m}In. The teachings of Edwards et al. do not include any suggestion that the in vivo imaging moiety should be selected from ^{18}F, ^{123}I.

19. The reference of Edwards et al. teaches that the imaging agent/detectably labeled MSRA disclosed in the present invention is an SR-A antagonist linked to a radioisotope, such as ^{18}F, ^{123}I, etc. in addition to metal chelates comprising a metal imaging moiety.

20. Applicant asserts that combining the teachings of Edwards et al. with those of Weinstock et al. also does not result in a sulphonamidobenzamide derivative labeled with ^{18}F or ^{123}I.

21. The reference of Weinstock et al. teaches of sulphonamidobenzamide macrophage scavenger receptor antagonists (MSRA) (below) for treating cardiovascular disease comprising halo substituents at the R_1 and/or R_2 positions .

22. 

(I)

23. The halo substituent (R_1 and R_2) positions on the MSRA antagonists of Weinstock et al. are identical positions found on the MSRA antagonists of the instant claims.

24. The reference of Edwards et al. was used to teach of detectably labeled macrophage scavenger receptor antagonist (MSRA) complexes for the diagnosis and monitoring of various cardiovascular diseases including but not limited to

atherosclerosis, coronary artery disease, renal disease, thrombosis, transient ischemia, etc. wherein the imaging agent/detectably labeled MSRA disclosed in the present invention is an SR-A antagonist linked to a radioisotope, such as ^{18}F, ^{123}I, etc.

25. At the time of the invention it would have been obvious to one ordinarily skilled in the art to substitute the radioisotope, such as ^{18}F, ^{123}I, etc. of Edward et al. for the halogen substituent of Weinstock et al. to provide SR-A antagonist imaging agents as the results are the predictable advantage of both treating and diagnosing/monitoring cardiovascular diseases.

26. Applicant's assertions with regard to the reference of Choi et al. are extraneous as the reference of Choi et al. is withdrawn from the rejection.

Conclusion

27. No claims are allowed at this time.

28. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any

extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to MELISSA PERREIRA whose telephone number is (571)272-1354. The examiner can normally be reached on 9am-5pm M-F.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Mike Hartley can be reached on 571-272-0616. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Michael G. Hartley/
Supervisory Patent Examiner, Art Unit 1618

/Melissa Perreira/
Examiner, Art Unit 1618